ADVATE 250IU, 500IU, 1000IU, 1500IU (human coagulation factor VIII (rDNA), octocog alfa)

ABBREVIATED PRESCRIBING INFORMATION

Please refer to full package insert before prescribing (29 May 2020/ U SmPC/CCDS v7.0)

Active Ingredient: Each vial contains nominally 250 IU, 500IU, 1000IU, 1500IU human coagulation factor VIII (rDNA), octocog alfa. **Indication:** Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency). ADVATE does not contain von Willebrand Factor and is therefore not indicated in von Willebrand's disease. **Posology and Administration:** The dose and duration of the substitution therapy depend on the severity of the factor VIII deficiency, on the location and extent of the bleeding and on the patient's clinical condition. Refer to package insert for guide for dosing in bleeding episodes and surgery. *Prophylaxis:* For long-term prophylaxis against bleeding in patients with severe hemophilia A, the usual doses are 20 to 40 IU of factor VIII per kg body weight at intervals of 2 to 3 days. *Paediatric population:* For on demand treatment dosing in paediatric patients does not differ from adult patients. In patients under the age of 6, doses of 20 to 50 IU of factor VIII per kg body weight 3 to 4 times weekly are recommended for prophylactic therapy. ADVATE should be administered via the intravenous route. The rate of administration should be determined to ensure the comfort of the patient up to a maximum of 10 ml/min. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 in the package insert or to mouse or hamster proteins. **Warnings and Precautions:** *Hypersensitivity:* Allergic type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. The product contains traces of mouse and hamster proteins. If symptoms of hypersensitivity occur, patients should be advised to discontinue use of the product immediately and contact their physician. Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. *Inhibitors:* The formation of neutralising antibodies (inhibitors) against factor VIII is a known complication in the management of individuals with hemophilia A. These inhibitors are usually IgG immunoglobulins directed against the factor VIII procoagulant activity, which are quantified in Bethesda Units (BU) per ml of plasma using the modified assay. In general, all patients treated with coagulation factor VIII should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed. *Catheter‑related complications in treatment:* If central venous access device (CVAD) is required, risk of CVAD‑related complications including local infections, bacteremia and catheter site thrombosis should be considered. *Excipient related considerations:* After reconstitution this medicinal product contains 0.45 mmol sodium (10 mg) per vial. To be taken into consideration by patients on a controlled sodium diet. **Interactions:** No interaction studies have been performed with ADVATE. **Fertility, Pregnancy and Lactation:** Animal reproduction studies have not been conducted with factor VIII. Based on the rare occurrence of hemophilia A in women, experience regarding the use of factor VIII during pregnancy and breast-feeding is not available. Therefore, factor VIII should be used during pregnancy and breastfeeding only if clearly indicated. **Driving:** ADVATE has no influence on the ability to drive and use machines. **Undesirable Effects:** Very common (≥1/10): Factor VIII inhibition (PUPs)*; Common (≥1/100 to <1/10):* Headache, Pyrexia. **Storage condition:** Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the vial in the outer carton in order to protect from light. For storage conditions after reconstitution of the medicinal product, see section 6.3 of package insert. **Name and Address of Product Registration Holder:** Takeda Malaysia Sdn Bhd, Unit TB-L13-1, Level 13, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor, Malaysia.

Further information is available on request.

Suspected Adverse events should be reported to Takeda at: AE.VMAPS@takeda.com

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